DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

93768

December 30, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gerald R. Vukman, DVM
7118 Orchard Park Road
Oakfield, NY 14125

File No.: NYK 2003-11

Dear Dr. Vukman:

An illegal residue investigation performed by U.S. Food and Drug Administration Investigator William P. Chilton included a visit to your veterinary practice on October 21 and 22, 2002. The investigation revealed that the drug [redacted] which you dispensed to [redacted] was responsible for an illegal tissue residue in a cow subsequently offered for slaughter for human food.

Flunixin residue was found in the liver tissue of a cow slaughtered on or about April 17, 2002. The cow was slaughtered at [redacted] The presence of this drug, at the reported level of 1.45 ppm in the edible tissue of this animal, causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). The fact that extra label usage of flunixin resulted in a residue which may present a risk to public health and which is above an established tolerance causes the drug to be adulterated under Section 501(a)(5) of the Act.

The flunixin residue in the cow resulted from the extra label use by [redacted] of [redacted] (flunixin meglumine) Injection, 50 mg/ml dispensed by you. The investigation revealed that [redacted] administered one 20 ml intramuscular injection of this drug to the cow two days before it was offered for sale. [redacted] is not approved for the treatment of lactating and dry dairy cows; therefore its use in the treatment of this lactating cow is considered extra label usage. The identity of the cow was not maintained and no follow-up examination was performed. You failed to institute procedures to maintain the identity of the treated cow, establish a substantially extended withdrawal period for beef supported by appropriate scientific information, and take appropriate measures to assure that assigned withdrawal times were satisfied.

The flunixin meglumine you dispensed is adulterated under Section 501(a)(5) and within the meaning of Section 512 of the Act. Section 512 deems, in part, a new animal drug is unsafe unless an FDA approved application is in effect and the drug, its labeling and use conform to such approved application or the implementing regulations for "Extralabel Drug Use in Animals", 21 Code of Federal Regulations (CFR) Part 530. The extra label use of approved veterinary or human drugs by veterinarians is allowed under the Animal Medicinal Drug Use Clarification Act (AMDUCA), provided that the regulations contained in 21 CFR Part 530 are followed.

21 CFR § 530.5 imposes recordkeeping requirements for veterinarians as a condition of prescribing drugs for extra label use. Our investigation revealed you are not complying with this regulation in that you did not maintain extra label treatment records for this cow.

21 CFR § 530.20(a)(2) discusses what the veterinarian is required to do prior to prescribing or dispensing an approved new animal drug for an extra label use. Specifically, the veterinarian must establish a substantially extended withdrawal period prior to marketing of meat products supported by appropriate scientific information, if applicable [21 CFR 530.20(a)(2)(ii)]; institute procedures to assure that the identity of the treated animal or animals is carefully maintained [21 CFR 530.20(a)(2)(iii)]; and take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animals subjected to extra label treatment [21 CFR 530.20(a)(2)(iv)]. The fact that a residue occurred from the extra label treatment indicates you did not comply with these parts of 21 CFR 530.20(a)(2).

The above is not intended to be an all-inclusive list of violations. When you administer and/or dispense an animal drug for extra label use in the treatment of disease conditions in food producing animals, you assume added responsibility. You must establish a substantially extended withholding period supported by appropriate scientific information, you must assure the identity of a treated animal and that treatment records are carefully maintained, and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and that no illegal residues occur. This includes assuring that your clients will follow your instructions.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that the extra label drug usage dispensed by you resulted in the adulteration of an animal that was subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, U.S. Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601, telephone 914-682-6166 x34.

Sincerely,

for Jerome G. Woyshner
District Director